EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2019
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2008 September 2008 November 2008 January 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 January 2009
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2009
Rediscussion in Working Party on Community monographs and Community list (MLWP)	July 2009 September 2009
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Taraxacum officinale* Weber ex Wigg., radix cum herba; Taraxaci radix cum herba; dandelion root with herb

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda): Pienenes saknes
DA (dansk):	MT (malti): Għerq iċ-Ċikwejra Salvaġġa
DE (Deutsch): Löwenzahnkraut mit Wurzel	NL (nederlands):
EL (elliniká):	PL (polski): Ziele mniszka z korzeniem
EN (English): dandelion root and herb	PT (português):
ES (espanol): Diente de león, parte aérea y raíz de	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français): Pissenlit (partie aérienne et racine de)	SV (svenska):
HU (magyar):	*IS (íslenska)*:
IT (italiano):	*NO (norsk):* Løvetann, urt med rot

1 Change introduced in section 2. Footnote 2 and 3 iadapted in September 2019

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Community herbal monograph on *Taraxacum officinale* Weber ex Wigg., radix cum herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended. Taraxacum officinale Weber ex Wigg., radix cum herba (dandelion root with herb). i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted dried root with herb b) Dry extract (DER 5.6-8.4:1), extraction solvent ethanol 60% (V/V) c) Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 30% (V/V) d) Liquid extract (DER 0.75:1), extraction solvent ethanol 30% (m/m) e) Expressed juice (DER 1:0.5-0.8) from fresh flowering Taraxaci radix cum herba [3]

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid or liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

2 The material complies with the Ph. Eur. monograph (ref.: 1851).

3 The material, when dried, complies with the Ph. Eur. monograph.

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication a) Traditional herbal medicinal product for the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion) and temporary loss of appetite. Indication b) Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Indication a) a) Comminuted dried root with herb, 3-4 g as a decoction or 4-10 g as an infusion up to 3 times daily b) 1 coated tablet, 300 mg dry extract, 2 times daily or 1-2 coated tablets, 150 mg dry extract each, 3 times daily c) Liquid extract 90 drops (90 drops = 3.15 ml = 3.31 g), 3 times daily d) Liquid extract 35 drops (35 drops = ca. 1 ml = 1 g), 3 times daily e) Expressed juice from fresh flowering Taraxaci

Well-established use	Traditional use
	radix cum herba Single dose 10 ml, 3 times daily Indication b) a) Comminuted dried root with herb, 3-4 g as a decoction or 4-10 g as an infusion up to 3 times daily The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. Indication b) To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family. Obstructions of bile ducts, cholangitis, liver diseases, gallstones, active peptic ulcer and any other biliary diseases.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in patients with renal failure and/or diabetes, and/or heart failure should be avoided because of possible risks due to hyperkalemia. The use in children under 12 years of age has not been established due to lack of adequate data. If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of

Well-established use	Traditional use
	the medicinal product, a doctor or a qualified health care practitioner should be consulted. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Epigastric pain and hyperacidity may occur. The frequency is not known. Allergic reactions may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

12 November 2009